

OCT 17 2005

**510(k) SUMMARY  
NEMOTO KYORINDO  
DUAL SHOT – CONTRAST DELIVERY SYSTEM**

DATE 510(k) SUMMARY PREPARED: July 26, 2005

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CLASSIFICATION NAME(S): Angiographic Injector with Syringe

DEVICE CLASSIFICATION: Class II

COMMON NAME: Powered Injector with Syringe

PROPRIETARY NAME: DUAL SHOT – CONTRAST DELIVERY SYSTEM

PREDICATE DEVICE: Stellant CT Injector System  
from MEDRAD K023183  
Stellant CT Injector System  
with Imaging System Interface Module  
from MEDRAD K033881

INTENDED USE: The DUAL SHOT – CONTRAST DELIVERY SYSTEM is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed X-ray tomography (CT).

**DESCRIPTION OF DEVICE:**

DUAL SHOT – CONTRAST DELIVERY SYSTEM is an Angiographic injector that is used in conjunction with X-ray Computed tomography, and is intended for use by doctors, radiologic technologists and other licensed medical practitioners. This device is designed to correspond to the various injection methods of contrast media which were materialized with the appearance of multi-slice CT scanners. The DUAL SHOT has two driving parts to deliver contrast media and/or saline, one side is for 50mL, 100mL and 200mL, size syringes, and the other side for 50mL syringes capable for saline flush injection. Syringes are connected to the patient via an intravascular catheter. DUAL SHOT consists following components;

- Injector head

Injector head provides accurate, automatic delivery of contrast media by two electromechanically driven actuators. Sterile empty-syringes or pre-filled syringes can be set onto the Injector head. For the sterile empty-syringes, Injector head provides auto-return function to fill the syringe with contrast media or saline. Injector head is composed of operation indicator LED, switches for manual operation, start-switch to start infusion and stop-switch to stop infusion. Injector head detects injection conditions and transmits the Injector head status information to the console.

- Console

The console takes up very little space on a control desk, and consists of TFT LCD display and touch panel interface to set/display various injections set by an operator. The operator can set injection pressure, time, volume, flow rate and a patient examination region of interest.

- Power Supply

The power supply is intended for placement on the floor around the console of a CT scanner. The power supply consists of a transformer and appliance inlet, as a provide power source to the injector head and console.

- Options

- Hand Switch

Hand Switch is connected to the console and consists of start and stop switches to start/stop injection according to the protocols already set on the console. Hand Switch provides LEDs with an operator to display scan time and injection state.

## SUBSTANTIAL EQUIVALENCE:

DUAL SHOT – CONTRAST DELIVERY SYSTEM maintains the same intended use as the predicate device. It is intended for the specific purpose of injecting contrast media and saline solution into a patient's vascular system to obtain diagnostic images in X-ray computed tomography (i.e. "CT").

DUAL SHOT – CONTRAST DELIVERY SYSTEM consists of three main components like the predicate device: a Injector head, a Console, and a Power Supply. Both the DUAL SHOT and predicate device consist of the same or substantially equivalent materials and technology. They are motor driven, electromechanical devices that are controlled by software.

Below is a table that compares the predicate device to the proposed DUAL SHOT – CONTRAST DELIVERY SYSTEM.

Feature	Proposed Device: <b>DUAL SHOT – CONTRAST DELIVERY SYSTEM</b>	Predicate Device: <b>Stellant CT Injector System (K023183 and K033881)</b>
Intended Use	The DUAL SHOT CONTRAST DELIVERY SYSTEM is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed x-ray tomography (CT).	Intended to be used for the specific purpose of injecting intravenous contrast media into humans for diagnostic studies in computed tomography (CT) applications.
Single or Dual Syringe System	Dual syringe model	Single and dual syringe models
Information Display	Color LCD	Same
Programming Keys	Non-dedicated keys – software determined	Same
Touch screen	Yes	Same
Multi-Phase	1-5 Phases per injection	1-6 Phases per injection
Arming Modes	Single	Same
Protocol Storage Capability	125 protocols	32 protocols
Hold capability	Until user operate.	20 minutes max.
Scan Delay	1 – 300 seconds	Same
Safety Stop Mechanism	Multi layered software stops with backup monitoring.	Electrical stop with a software backup system
Syringe System	A-head: 200mL or 100mL syringe B-head: 50mL syringe	Dual syringe model: two 200mL syringe
Programmed Volume	A-head: 1 to 200mL or 1 to 100mL (depending on syringe size) B-head: 1 to 50mL	1 to 200mL
Volume Remaining Readout	Graphical and numeric on LCD	LED on injector head; graphical and numeric on LCD
Fill Rate	Variable up to 10mL/sec	Same
Flow Rate	0.1mL/sec to 10mL/sec	Same
Programmable Pressure Limit	Settable from 10 to 300PSI	325PSI default, user settable 50 to 300 PSI
Pause	Programmable – 1 sec to 300 seconds in 1 sec increments	Programmable – 1 sec to 900 sec in 1sec increments
Autofill	Fill rate 1.5mL/sec	Fill rate 4mL/sec
Retract Control	No	Yes (Automatic)
Remote Start Switch	Yes	Yes
Pressure Graph	Yes	Yes
Syringe Sensing	Yes	Yes
Autoload	No	Yes
Auto Dock/Retract/Advance	No	Yes; user-selectable autodock and advance; user-selectable auto-retract
Protocol Lock/ Remote Arming	No	Yes
Remote Check for Air (from Head)	No	Yes
Test Injection	Yes	Yes
Syringe Heat Maintainer	Yes	Yes

## PERFORMANCE DATA:

No performance standards have been established for Angiographic injectors under section 514 of the FD&C Act.

DUAL SHOT CONTRAST DELIVERY SYSTEM has been tested in conformance with the following recognized standards, and is substantially equivalent to the predicate device:

IEC60601-1 (1988) Medical Electrical Equipment, Part 1: General Requirements for Safety - This is the general standard for medical electrical equipment  
IEC60601-1-1 (2000) Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems  
IEC60601-1-2 (2001) Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests  
IEC60601-1-4 (1996) Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems  
ISO13485 (2003) Medical devices - Quality management systems - Requirements for regulatory purposes  
ISO14971 (2000) Medical devices - Application of risk management to medical devices

Biocompatibility testing has not been performed since DUAL SHOT - CONTRAST DELIVERY SYSTEM does not include a sterile syringe.



OCT 17 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Tuv Rheinland of North America, Inc.  
c/o Mr. Tamas Borsal  
Manager, Medical Division  
12 Commerce Road  
Newton, CT 06470

Re: K052633  
Dual Shot – Contrast Delivery System  
Regulation Number: 21 CFR 870.1650  
Regulation Name: Angiographic Injector and Syringe  
Regulatory Class: II  
Product Code: DXT  
Dated: September 20, 2006  
Received: September 26, 2005

Dear Mr. Borsal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Page 2 – Mr. Tamas Borsal

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known) : K052633

Device Name : Dual Shot – Contrast Delivery System

Indications For Use:

The Dual Shot – Contrast Delivery System is an intravascular injection system intended for the administration of ionic and non-ionic contrast media and saline used in conjunction with computed X-ray tomography (CT).

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

Diana R. Lechner  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K052633